



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,897	04/20/2004	Michael Paris	A04P3006-US1	6172

24473 7590 09/29/2005

STEVEN M MITCHELL  
PACESETTER INC  
701 EAST EVELYN AVENUE  
SUNNYVALE, CA 94086

EXAMINER
----------

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,897	<b>Applicant(s)</b> PARIS, MICHAEL	
	<b>Examiner</b> Jessica L. Reidel	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/20/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Claims 1-5 and 13-14 in the reply filed on September 15, 2005 is acknowledged.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Ternes (U.S. 2005/0065443). As to Claims 1 and 3, Ternes discloses an implantable medical device 102 that monitors a changing heart rate of a patient and produces heart rate measurements (see Ternes Fig. 7, page 4, paragraph 34 and page 5, paragraphs 42-43), identifies an onset of an exercise episode when at least one of the following two conditions occur: at least one heart rate measurement exceeds a first heart rate measurement threshold R1 and/or at least one sensor output, read as an activity level, exceeds a first activity level threshold S1, identifies an end of an exercise episode when at least one of the following two conditions occur: at least one heart rate measurement falls below a second heart rate measurement threshold R2 and/or at least one sensor output, read as an activity level, falls below a second activity level threshold S2 (see

Art Unit: 3762

Ternes page 3, paragraphs 27-28), and uses the exercise episode and end of the exercise episode to determine a measure of heart rate recovery (see Ternes Fig. 10, page 3, paragraph 30 and page 6, paragraph 50). It is inherent that the onset of an exercise episode and the end of an exercise episode comprise identifying a first heart rate and a second heart rate since heart rate versus time is plotted during the entire episode via display 226 (see Ternes Fig. 7 and page 5, paragraph 43).

4. As to Claim 14, Ternes discloses a technique of displaying heart rate recovery by drawing a line 1000 extending from the beginning 1002 of the recovery period to the end 1004 of the recovery period and the slope of that line illustrates the average time rate of change of the heart rate during the recovery period. Ternes also discloses that the user may move cursers 1002 and 1004 and calculate heart rate recovery 1102, 1104 and 1106 at any time interval. It is inherent that the second heart rate is subtracted from the first heart rate to determine a measure of heart rate recovery when 1102, 1104 and 1106 are determined from the slope of a line starting from the onset of an exercise episode and the end of an exercise episode (see Ternes page 6, paragraphs 50-51).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ternes in view of Imran et al. (U.S. 4,393,877) (herein Imran). Ternes discloses the claimed invention as

Art Unit: 3762

discussed above except that identifying a first heart rate does not further comprise identifying the first heart rate when at least one heart rate measurement exceeds the first heart rate measurement threshold R1 for a predetermined period of time.

Imran, however, discloses an improved heart rate detector apparatus 2 for use with an implantable medical device that includes a heart rate comparator that compares a detected heart rate with a predetermined rate, read as a predetermined threshold, and, if the heart rate exceeds the predetermined rate for a predetermined time period, provides an output (see Imran Abstract and column 4, lines 43-57). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ternes in view of Imran to provide an improved method and apparatus of heart rate detection in order to better the invention.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ternes in view of Thong (U.S. 2003/0187479). Ternes discloses the claimed invention as discussed above except that the method does not further comprise a step of filtering heart rate measurements to remove premature heartbeats.

Thong, however, discloses an implantable medical device 4 for detecting a prolonged pattern of increasing heart beat rate which first measures R-R intervals and then filters out premature beats via filter 241 (see Thong page 5, paragraph 60 and page 6, paragraph 61). Thong does not explicitly state why the filter for premature beats 241 is used, but it appears that the filter is used to increase the accuracy of the long-term heart rate determination from the sensed R-R intervals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Ternes as taught by Thong, with a filter for

Art Unit: 3762

premature beats, since such a modification would provide the method with increased accuracy in continuous heart rate determination.

### *Conclusion*

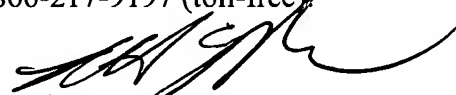
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Snell (U.S. 6,904,313) discloses methods and systems for monitoring heart rate recovery where an implantable monitoring device monitors a patient's heart activity and looks for periods of increased activity, such as those that are experienced during some level of exercise, and periods of lesser activity (such as rest) directly following. The patient's heart rate recovery is monitored as the heart recovers from the active period to the rest period. Starobin et al. (U.S. 2003/0149370) discloses a method that comprises the steps of: (a) collecting a first RR-interval data set from said subject during a stage of gradually increasing heart rate up to a predetermined heart rate of at least 130 beats per minute; (b) collecting a second RR-interval data set from said subject during a stage of gradually decreasing heart rate; (c) comparing said first RR-interval data set to said second RR-interval data set to determine the difference between said data sets; and (d) generating from said comparison of step (c) a measure of cardiac ischemia during stimulation.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3762

Jessica L. Reidel 